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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/888,008	06/22/2001	Thomas P. Karsten	3352/US	8520

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PHARMACIA CORPORATION
GLOBAL PATENT DEPARTMENT
POST OFFICE BOX 1027
ST. LOUIS, MO 63006

EXAMINER

GITOMER, RALPH J

ART UNIT PAPER NUMBER

1651

DATE MAILED: 02/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/888,008

Applicant(s)

KARSTEN ET AL.

Examiner

Ralph Gitomer

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Applicant's election without traverse of Group I, claims 1-21, in Paper No. 5 is acknowledged. Priority is granted to 6/22/2000.

The point of novelty appears to be directed to separating the unreacted substrate from the product with ion exchange resin to make an enzyme determination.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-6, 8-11, 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Cerretani.

Cerretani (Anal Biochem) entitled "A High Throughput Radiometric Assay for Hepatitis C Virus NS3 Protease" teaches in the abstract, reacting a protease with a substrate and separating the substrate from the product with ion exchange resin. The assay was performed in a microtiter plate format and has the potential for using a robot. On page 194, the reaction was performed in a 96 well microplate. On page 195 Fig. 2 shows a curve where the reaction was stopped before all the substrate had been converted to the product. Also on page 195 column 2, inhibition of enzyme activity was studied, see Fig. 3 on page 196. On page 196 column 2 the assay is amenable for automated high throughput screening.

All the features of the claims are taught by Cerretani for the same function as claimed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 4, 7, 12, 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Cerretani in view of each of Sandmann and Strulovici.

Cerretani (Anal Biochem) entitled "A High Throughput Radiometric Assay for Hepatitis C Virus NS3 Protease" teaches in the abstract, reacting a protease with a substrate and separating the substrate from the product with ion exchange resin. The

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assay was performed in a microtiter plate format and has the potential for using a robot. On page 194, the reaction was performed in a 96 well microplate. On page 195 Fig. 2 shows a curve where the reaction was stopped before all the substrate had been converted to the product. Also on page 195 column 2 inhibition of enzyme activity was studied, see Fig. 3 on page 196. On page 196 column 2 the assay is amenable for automated high throughput screening.

The claims differ from Cerretani in that claim 4 specifies the substrate rather than the product is bound to the resin, in claims 7, 12 and 14 the enzyme assayed is a kinase or other specific enzyme, and in claim 15 an isozyme control is employed.

Sandmann (*Physiologia Plantarum*) entitled "Assays for Three Enzymes Involved in Mevalonic Acid Metabolism" teaches in the abstract, kinase enzyme assays where labeled substrates are reacted and separated by anion exchange chromatography. On page 300 column 2, the assays are used for determination of enzyme activities.

Strulovici (5,759,787) entitled "Kinase Assay" teaches in column 4 lines 39-52, high throughput kinase assays are shown with microtiter plates. In column 2 the product is bound and detected. See the claims.

It would have been obvious at the time the invention was made to one of ordinary skill in this art to bind any desired component of the reaction to the resin to determine enzyme activity because no criticality is seen in the selection and the references cited herein show various different methods where different components are bound to the resin.

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Regarding the selection of enzyme to study, Cerretani is directed to a protease and each of Sandmann and Strulovici are directed to kinases. To apply a known method for determining enzyme activity of one type of enzyme to another known type of enzyme would have been obvious because this is standard in this art and one would have a high expectation of success. The secondary references employ closely related methods to the primary reference for determining kinases. Present claim 12 has a Markush group of a number of types of enzymes which are considered equivalents in the claimed invention and include peptidase and kinase.

Regarding claim 15, controls are well known and shown throughout the cited references for determining enzyme activity. No novelty is seen in selecting an isozyme as a control.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 15 is queried regarding where in the specification the method and its results are taught. further, since an isozyme would be known to have similar activity to the primary enzyme, what the significance of such a determination would be is not seen.

Claim 16 is directed to determining bi-functional enzyme activity, claim 19 is directed to determining kinetics of an enzyme reaction, claim 20 is directed to a method of determining the functional sites on an enzyme, and claim 21 is directed to a method of evaluating the selective coupling of an enzyme and a reactant. The specification fails to teach one of skill in this art how to perform any of these claimed functions, and no description, examples or results are shown. The difficulty in accurately performing these functions is known in this art.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Each of the following applies in each and every occurrence.

In claim 1 and all the independent claims, there is no step in the claim to perform the preamble. A correlating step is suggested. Claim 10 is not understood in context where formats are not seen to be automated. In claim 11 "said high-throughput" lacks

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antecedent basis. In claim 12 and all occurrences, please spell out the name of each substance in the first occurrence in the claims. Note in claim 12 and other instances, there are two commas after GTase. In claim 15 "izozyme" is queried. In claim 15 line 3, "effects" may be intended to of "affects". In claim 18 "said determination" lacks definite antecedent basis and it is unclear as to what is conducted separately from what. In claim 19 line 1, "the kinetics" lacks antecedent basis. In claim 19 line 6, "the reaction" lacks antecedent basis.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Zhu (6,171,810) teaches assaying glycosidase activity.

Sherf (5,744,320) teaches enzyme assays.

Alajoki (6,416,642) teaches microscale channels.

Loehrlein (6,618,679) teaches microfluidic devices.

Nelson (US 2002/0119482 A1) teaches ion exchange purification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone

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number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ralph Gitomer
Primary Examiner
Art Unit 1651

RALPH GITOMER
PRIMARY EXAMINER
GROUP 1200